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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/802,644 | 03/17/2004 | Linda D. Martin | 5051-574CT | 3963 |

20792 7590 10/06/2006

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

| EXAMINER | |
|---|---|
| HADDAD, MAHER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/802,644 | MARTIN ET AL. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *52-54,57-67,70-75 and 85-91* is/are pending in the application.

4a) Of the above claim(s) *54,67,85,87,88 and 90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-53, 57-66, 70-75, 86, 89 and 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 7/11/06, is acknowledged.

2. Claims 52-54, 57-67, 70-75 and 85-91 are pending.

3. Claims 54, 67, 85, 87-88 and 90 (non-elected species) are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected species. See MPEP 803.02.

4. Claims 52-53, 57-66, 70-75, 86, 89 and 91 are pending and under examination in the instant application as they read on a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof wherein inflammation is respiratory diseases and COPD as the species.

5. In view of the amendment filed on 7/11/06, only the following rejections are remained.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

7. Claims 52-53, 57-66, 70-75, 86, 89 and 91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the MARCKS protein-related release of mucus hypersecretion comprising administering to a subject suffering from asthma a pharmaceutical composition comprising a MANS peptide consisting of the amino acid sequence of SEQ ID NO: 1, does not reasonably provide **enablement** for a method of inhibiting the MACKS protein-related release of any "inflammatory mediator" in a subject comprising administering to a subject suffering from "inflammation" a therapeutically effective amount of a pharmaceutical composition comprising a MANS peptide consisting of an amino acid sequence of SEQ ID NO:1 in claim 52, wherein said inflammation is caused by any "respiratory disease" in claim 53, or COPD in claim 86 or a method of inhibiting the MARCS protein-related release of any "inflammatory mediator" from any "infiltrating inflammatory cell in a subject suffering from "inflammation" caused by any "disease or condition" involving inflammation comprising administering to said subject a therapeutically effective amount of a pharmaceutical composition comprising a MANS peptide consisting of an amino acid sequence of SEQ ID NO:1 in claim 64, wherein said inhibiting the MARCKS protein-related release of an inflammatory mediator comprise blocking or reducing the MARCKS protein-related release of any "inflammatory mediatory" from said infiltrating inflammatory cell in claim 65, wherein said inflammation is caused by any "respiratory disease" in claim 66, or COPD in claim 89. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 1/11/06.

In view of Dr. Rogers' declaration dated 7/11/06, the specification is enabled for a method of inhibiting the MARCKS protein-related release of mucus hypersecretion comprising administering to a subject suffering from asthma a pharmaceutical composition comprising a MANS peptide consisting of the amino acid sequence of SEQ ID NO: 1. It is noted that Dr. Rogers' declaration contains alteration by strikethrough the word "*in vivo*" without initialing and dating the alteration.

Applicant's arguments, filed 7/11/06, have been fully considered, but have not been found convincing.

Applicant does not understand the Examiner's rationale for discussing the state of the art in treating only airway mucus hypersecretion and utilizing the Rogers 2003 and Barnes 2002 publication. Applicant states that even more confusing are the Examiner's comments that the specification relies upon inhibiting mucin secretion by the MANS peptide as an assay to determine MANS peptide activity and the specification discloses no efficacy. Applicant points to Dr. Rogers declaration under 1.132 to question the relevance of the Examiner's use of Rogers 2003 and Barnes 2002 publications in support of the lack of enablement. Applicant submits that based on Dr. Rogers Declaration the present invention is directed to inhibiting the MARCK protein related release of an inflammatory mediator and his knowledge in the field of respiratory physiology that mucus hypersecretion does not cause inflammation of the airways, he does not find the publications cited by the Examiner to be relevant to determine whether the claimed invention is enabled. Yet, Dr. Rogers address the Examiner's basis for lack of enablement to maintain normal mucus secretion while inhibiting mucus hypersecretion.

However, the Examiner is confused by the Applicant's confusion over the rationale for discussing the state of the art in treating only airway mucus hypersecretion and utilizing the Rogers 2003 and Barnes 2002 publications. The previous rejection mailed on 1/11/06, specifically state that at issue, whether 1) the claimed methods would work in vivo. While Dr. Rogers 2003 article may not address the MARCK-related release of inflammatory mediators however, the use of Dr. Rogers 2003 article is relevant because the specification on ¶9 discloses mechanisms responsible for secretion of inflammatory mediators from inflammatory cells may also lead to the ability to inhibit both types of secretion (mucus and inflammatory mediators) via targeting an intracellular molecule or event common to both types of secretory pathways. Further, canceled claim 76 claims a method of inhibiting inflammatory mediators *and* mucin secretion with SEQ ID NO:1.

In response to the issue on page 2, ¶2 of the declaration that mucus hypersecretion does not cause inflammation of the airways. Accordingly, Dr. Rogers concludes that we would not find these publications particularly relevant regarding the state of the art in inhibiting the release of MARCKS related inflammatory mediators in a subject suffering from inflammation.

The Examiner agrees with Dr. Rogers' statement to the extent that the mucus hypersecretion does not cause inflammation of the airways. However, it is noted that the previous office action states that the state of the art is that current treatments of diseases ***associated*** with airway mucus hypersecretion, the Office Action does not state, as in Dr. Rogers' declaration, that the mucus hypersecretion cause inflammation. It is not clear as why Dr. Rogers addressing this issue. The relevancy of the references came for Applicant's own disclosure that mechanisms responsible for secretion of inflammatory mediators from inflammatory cells may also lead to the ability to inhibit both types of secretion (mucus and inflammatory mediators) via targeting an intracellular molecule or event common to both types of secretory pathways (see ¶9 of the specification).

In response to Dr. Rogers' declaration on ¶3, that anti-MARCKS therapy for airway mucus hypersecretion merits consideration citing Li et al 2002 (exhibit 3), as the examiner state in the instant office action that a method of inhibiting the MARCKS protein-related release of mucus hypersecretion comprising administering to a subject suffering from asthma a pharmaceutical composition comprising a MANS peptide consisting of the amino acid sequence of SEQ ID NO: 1 is enabled. Dr. Rogers's declaration states that Li et al publication say nothing about the inhibition of MARCKS-related release of *inflammatory mediators* and accordingly not relevant to show the state of the art for the claimed invention. Similarly, the examiner concludes that since Li et al is silent with respect to inhibition of MARCKS-related release of inflammatory mediators this publication provides insufficient enablement for the claimed method of inhibition of MARCKS-related release of *inflammatory mediator.*

It noted that Applicant fails to address the issue raised by the examiner in the previous Office Action, mailed 1/11/06, that is whether the claimed methods would work in vivo.

Applicant directs the Examiner's attention to Nguyen et al (attachment C) which provide an example in which the in vivo activity related to a myelperoxidase-dependent pathway can be predicted by an in vitro myelpersoidase assay. Applicant asserts that the present application provides two examples with data showing in figures 9 and 10 of in vitro assays that the MANS peptide inhibits the release of MOP. Applicant direct the Examiner's attention to Takashi et al (attachment D) who provides additional in vitro examples of other inflammatory enzymes that also are inhibited by the MANS peptide.

Neither Nguyen et al Nor Takashi et al references address the issue at hand because therir teachings are not analog to the claimed methods of inhibiting the MARCS protein-related release of any "inflammatory mediator" with SEQ ID NO:1 *in vivo* as claimed herein. Applicant's claims are drawn to the inhibition of release of any inflammatory mediators, including antiinflammatory mediators (e.g., IL-10, CO) and proinflammatory mediators (e.g., TNF-α, IL-1β, and NO). The specification only discloses the in vitro inhibition of MOP with SEQ ID NO:1. Neither the exemplary embodiments nor the specification's general method appears to describe structural features that are common to the genus. That is, the specification provides neither a representative number of species (inflammatory mediators) to describe the claimed genus, nor does it provide a description of structural features that are common to species (inflammatory

mediators). The specification provides no structural description of inflammatory mediators other than the one specifically exemplified, i.e., MOP; in essence, the specification simply directs those skilled in the art to go figure out for themselves what the claimed inflammatory mediators looks like. The specification's disclosure is inadequate to describe the claimed genus of inflammatory mediators.

Regarding the point that Applicant is making regarding Dr. Kenneth Adler's declaration in Haile et al article that even in the absence of inflammation in the airways, there was still mucus hypersecretion. In addition, the presence of mucus hypersecretion did not cause inflammation, as there was not recruitment of inflammatory cells in the animals treated with vinblastine, which also showed mucus hypersecretion. The examiner agree with Dr. Adler's statement to the extent that while the presence of mucus hypersecretion do not cause inflammation, however the presence of mucus hypersecretion provide a favorable environment for bacterial growth, shelter for bacterial for the host inflammatory response. That is the inflammation is associated with hypersecretion. Further, Haile et al article is silent with respect to release of inflammatory mediators.

Regarding applicant comment about the lysis of eosinophils being more important than degranulation. Applicants state that they fail to see how this observation would make it unpredictable as to whether MANS peptide would be effective. The Examiner notes that the claims now are limited to inhibiting the release of inflammatory mediators and claim 76 is canceled. Therefore the argument is moot. Since Applicant raises the issue, the examiner position is that since eosinophils lysis, the contant the eosinophils is released and therefore, the claimed peptide would not inhibit the release of a lysed eosinophils cell. Further, the Examiner notes that claims are not limited to neutophils but the claims recite that the inflammatory mediators released by cells such as eosinophils (see pending claims 61 for example).

Regarding applicant comments about Abdel-Latif et al and Lacy et al, Applicant did not address the examiner's concerns regading the model using the references.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 52-53, 57-62, 64-66, 70-74, 89 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adler et al (CHEST. May, 2000, of record), as is evidenced by the specification on page 26, lines 11-15 for the same reasons set forth in the previous Office Action mailed 1/11/06.

Applicant's arguments, filed 7/11/06, have been fully considered, but have not been found convincing.

Applicant submits that the Examiner is erroneously relying on the first sentence of the Adler abstract for motivation to support his position that the claims are obvious over the Adler abstract. Applicant submits that the sentence "hypersecretion of mucus contributes to air way inflammation and obstruction in COPD" was not intended to establish a causal link that mucus hypersecretion causes inflammation. Applicant draws the Examiner's attention to Dr. Rogers' declaration for support that the first sentence in the Adler abstract does not suggest to him that inhibition of mucus hypersecretion will inhibit inflammation in the airways because mucus hypersecretion does not have a direct effect on inflammation. Applicant states that should the Examiner find Dr. Roger's statement persuasive, he would not be motivated by the Adler abstract to administer the MANS peptide to inhibit MARCKS-related release of inflammatory peptides.

The Examiner's agrees with both Dr. Adler and Dr. Rogers' declaration to the extent that that excess mucus built up make the airways susceptible to microbial infection which results in inflammation. That is inflammation is associated with mucus hypersecretion. However, the skilled in the art would still have been motivated to inhibit the excess mucus in the airway to prevent inflammation caused by microbial infection. Adler et al reference teachings arrive to the claimed invention. Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY ); and In re Burckel 201 USPQ 67 (CCPA).

Applicant contends that there is no disclosure in Adler et al that dephosphorylated MARCKS which attaches to mucin granule membranes will also attach to any part of an inflammatory cell, nor is there any information provided that points to the novel concept of MARCS attaching to an inflammatory cell; nor is there any disclosure that dephosphorylated MARCKS mediates granule release in an inflammatory cell, nor there any disclosure of the novel concept that a synthetic peptide with a sequence identical to the myristic acid containing N-terminal region of the MARCKS protein would inhibit release of any entity in or on or from an inflammatory cell. Applicant argues that these novel concepts from the essence of discovery that lead to the current invention as now more clearly claimed in the amended claims. The separate biological functions

of inflammatory cells and of mucin goblet cells suggest to one skilled in the art at the time the application was filed that separate mechanisms of biological action should apply rather than a common mechanism to link the diverse function of these two classes of cells. Applicant contends that the presence of two different cell types within a subject, one of which is migratory, with the two cell types having two separate and different biological functions is not sufficient to suggest to one skilled in the art that a common mechanism or common mediator would interact with each cell type. Only in retrospective analysis in view of the disclosure of the current invention is such a connection possible.

However, Applicant argues limitations that are not claimed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). See MPEP 2145. Further, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Even though applicant has proposed or claimed the mechanism by which a particular for the release of inflammatory mediators and alleviates symptoms of CODP does not appear to distinguish the prior art teaching the same methods to achieve the same end results. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Applicant submits that the Examiner's interpretation of Adler's abstract is that it would be obvious to anyone with a knowledge in the field that the myristic acid containing N-terminal region of the MARCKS protein also would block release of inflammatory mediators. Applicant submits that this is simply not the case and that it would not be obvious or even presumptive to think that unless the entire mechanism was understood.

It appears that applicant and the examiner differ on interpretation of both the claimed methods and the prior art. As pointed out above; the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Also, a species reads on a genus. It appears that applicant's arguments are consistent that the prior art does read on the claimed invention but differs primarily on an asserted mechanisms of action. Again, the mechanism of action disclosed by the prior art does not preclude that the methods and a synthetic peptide with a identical to the myristic acid containing N-terminal region of MARCKS protein of Adler et al. inherently would have had the properties of inhibiting the release of inflammatory mediators recited in the claims because the resultant methods and compositions comprising the same synthetic peptide with a identical to the myristic acid containing N-terminal region of MARCKS protein is administered to the same patients to treat the same with COPD condition to achieve the same result, that is, treating patients with COPD.

Again Applicant points out that excess mucus does not cause infection or inflammation but rather under certain conditions it may contribute to an environment for microbial growth which

could result in inflammation. Applicant submits that inhibition mucus cannot protect a subject from these infectious agents.

However, the Adler et al abstract arrived to the same end results as claimed invention, that is to inhibit inflammation in COPD subject with SEQ ID NO:1 (two mechanisms with the same peptide to treat COPD/inflammation). The prior art and applicant have suggested different mechanisms. It is acknowledged that applicant now believes in a different mechanism of action than the prior art. However, the instant methods do not negate or preclude the mechanism of action indicated by the prior art nor does applicant provide objective evidence to distinguish the prior art from the claimed invention.

10. Claims 63 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adler et al (CHEST. May, 2000, of record), as is evidenced by the specification on page 26, lines 11-15, as applied to claims 52-62, 64-74 and 76-83 above, and further in view of U.S Patent No. 6,506,779 of record for the same reasons set forth in the previous Office Action mailed 1/11/06.

Applicant's arguments submitted 10/31/05, has been fully considered, but have not been found persuasive.

Applicant argues that the `779 patent relates to acetylene derivatives, methods of treatment and pharmaceutical compositions for the treatment of cyclooxygenase mediated diseases. It does not in any way discuss or even contemplate the MANS peptide or a MARCKS related protein. Applicant submits for the same reasons above the Adler abstract either alone or in combination fail to contain any motivation to combine their teachings as required by In re Sang-su Lee.

However, based on the totality of the record as detailed above, the evidence of obviousness found in the combined reference teachings with Applicant's argument for nonobviousness. The Examiner concludes that the claimed invention encompassed by instant claims would have been obvious as a matter of law under 35 U.S.C 103(a).

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 52-53, 57-62, 64-66, 70-74, 89 and 91 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-79, 82, 85-87, 89, 95-96, 99-103, 105-106 and 111-114 of copending Application No. 09/914,020. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the instant claims are drawn to methods of inhibiting inflammatory mediators released from inflammatory cells while the `020 application claims are drawn to methods of inhibiting mucus secretion by a mucus-secreting cell from epithelia cells using the same peptide of SEQ ID NO:24, both the instant claims and the `020 application claims drawn to the treatment of the same patient populations with the same compositions to achieve the same therapeutic effect.
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues that the underlying basis for making this refection is misguided. Applicant submits that it is known by persons skilled in the art that any inflammatory cell that are present in inflamed tissue caused by a disease would be present in the sub-mucosal tissue and not in the epithelium that contains the epithelial goblet cells that secrete the mucus. Applicant further argues that the `020 application are directed to treating mucus hypersecretion by inhibiting mucus hypersecretion by a mucus-secreting epithelial cell contained with the airway and the claims of the present application are directed to treating inflammation by inhibiting the release of inflammatory mediators for inflammatory cells in the tissue. Applicant points out that the separate biological functions of inflammatory cells an of mucin epithelial goblet cells do nto suggest to one skilled in the art at the time the present application was filed that treatment of one type of cell to inhibit mucus hypersecretion would inhibit the release of inflammatory mediators from infiltrating cells. Applicant submits that a person skilled in the art would have recognized that these are separate mechanisms of biological action rather that a common mechanism to link the diverse function of these two classes of cells.

Applicant is reminded that under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02. As pointed out previously, the mechanism of action does

not have a bearing on the patentability of the invention if the invention was already known or obvious. It is clear that both the `020 application and the instant application administer the same composition comprising the same MANS peptide to the same patient to achieve the same results.

Applicant points out that the claims of the `020 application have not yet issued, Applicant concludes that the specific language of these claims are not finalized to allow the Examiner to make a determination that the presently pending claims are obvious over those of the pending claims of the `020.

However, the rejection was made under a provisional obviousness-type double patenting.

13. Claims 63 and 75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 77-79, 82-87, 89-90, 95-96, 98-103 and 105-106 of copending Application No. 09/914,020 in view of U.S Patent No. 6,506,779 of record for the same reasons set forth in the previous Office Action mailed 1/11/06.

Applicant's arguments, filed 7/11/06, have been fully considered, but have not been found convincing.

Applicant argues that the `779 patent does not cure the defects of the `020 application.

However, based on the totality of the record as detailed above, the evidence of obviousness found in the combined reference teachings with Applicant's argument for nonobviousness. The Examiner concludes that the claimed invention encompassed by instant claims would have been obvious as a matter of law under 35 U.S.C 103(a).

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 20, 2006

Maher Haddad

Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600